INTELLIGENT MEDICAL DEVICE BARRIER

Cross Reference to Related Application

This application claims the benefit of U.S. Provisional Patent Application No. 60/425,784, filed November 12, 2002, the entirety of which is hereby incorporated by reference into this application.

Background of the Invention

1. Field of the Invention

The present invention relates to an intelligent medical device barrier to sense when a barrier is properly attached to a medical device thereby insuring proper use and single use of the barrier.

2. Description of Related Art

Various medical devices are used in medical procedures. If the medical device can be re-used, it is desirable to assure cleanliness of the device. Conventional methods for sterilizing medical devices include heating, washing and covering of the medical device during use.

U.S. Patent No. 6,142,959 describes using a thin elastic protective film to cover a probe head and shaft during use. The thin elastic cover is held by a fixing ring to the handle. The thin elastic cover can be removed from the probe and discarded. Thereafter, a new thin elastic cover can be placed over the shaft before the next use for providing improved hygienics of the prostate examination.

U.S. Patent No. 6,582,368 describes a medical instrument sheath formed of a body of a nonconductive material. A piezoelectric copolymer transducer is held snugly against the medical device by the sheath body. The sheath body may be constructed of a shrink tube such as polytetrafluorethylene which shrinks when exposed to heat. After use, the sheath is removed from the medical device and discarded. The medical device may then be used either in conjunction with another sheath or alone. The sheath may also be used in conjunction with a disposable medical device, where both the sheath and the device are disposed of at the end of the procedure. No prior art of which applicant is aware, provides a mechanism for insuring that the elastic cover has been used for a single procedure.

It is desirable to provide a medical device barrier to communicate with a medical device and to assure single use of the barrier.

Summary of the Invention

The present invention relates to an intelligent medical device barrier in which a barrier includes sensory means to determine if the cover is in place properly and insure single use of the barrier. The sensory means allows one set of readings to be taken using the medical device. The sensory means can provide a lot number, serial number or calibration data to the medical device. After use of the medical device barrier, the sensory means prevents re-use of the barrier for a subsequent procedure. The medical device barrier covers all surfaces of the medical device which contact tissue to prevent viral or bacterial transmission. For example, in a probe device the barrier covers the probe shaft and probe sensor area in order to prevent probe contact with patient tissue. The invention will be more fully described by reference to the following drawings.

Brief Description of the Drawings

Fig. 1A is a perspective diagram of an intelligent medical device barrier attached to a probe in accordance with the teachings of the present invention.

Fig. 1B is a cross sectional view of the intelligent medical device barrier and probe shown in Fig. 1A.

Fig. 2A is a perspective view of an alternative intelligent medical device barrier.

Fig. 2B is a cross sectional view along line A-A of Fig. 2A.

Fig. 2C is a cross sectional view along line B-B of Fig. 2A.

Fig. 2D is a cross sectional view along line C-C of Fig. 2A.

Fig. 3A is a perspective view of an alternate embodiment of an intelligent medical device barrier attached to a probe.

Fig. 3B is a top plan view of a probe handle used with the intelligent medical device barrier shown in Fig. 3A.

Fig. 3C is a side elevational view of the probe handle shown in Fig. 3B.

Fig. 3D is a cross sectional view of the probe handle receiving the medical device barrier.

Fig. 3E is a bottom plan view of the probe handle shown in Fig. 3B.

Detailed Description

Reference will now be made in greater detail to a preferred embodiment of the invention, an example of which is illustrated in the accompanying drawings. Wherever possible, the same reference numerals will be used throughout the drawings and the description to refer to the same or like parts.

Figs. 1A and 1B are schematic diagrams of an embodiment of an intelligent medical device barrier 10 in accordance with the teaching of the present invention. Cover 12 is formed of a similar shape of probe head 13 and probe handle 14 of probe 11. Cover 12 is received over tip 8 and probe head 13 and is pulled or rolled up over shaft 9 of probe head 13 in order to be used as a barrier to probe 11. Cover 12 can be received over portion 7 of probe handle 14 for insuring shaft 9 is completely covered by cover 12. For example, probe 11 can be a probe used for examination of the prostate as described in U.S. Patent No. 6,142,959, hereby incorporated by reference into this application.

Retaining means 15 secures cover 12 in place on probe handle 14. For example, retaining means 15 can be a detent, tab, snap catch, hook or ring for coupling cover 12 to probe handle 14 which inserts, snaps or twists into place on probe handle 14. Retaining means 15 provides expeditious attachment of cover 12 to probe head 13. For example, cover 12 can be installed or removed on probe head 13 and probe handle 14 in less than about 10 seconds. Retaining means 15 can be coupled to cover 12. Alternatively, retaining means 15, such as a ring, can be placed over cover 12 to press cover 12 against probe handle 14.

One or more sensors 16 can be attached to one or more predetermined positions on handle 14, retaining means 15 or cover 12 for sensing when cover 12 is in place properly on probe head 13. In one embodiment illustrated in Fig. 2A, sensor 16 is coupled to retaining means 15 and retaining means 15 is attached to cover 12. Retaining means 15, such as a detent, is coupled to an indentation or protrusion in probe handle 14. Upon probe handle 14 engaging retaining means 15, sensor 16 is activated to indicate that cover 12 is in place on probe handle 14. If it is determined cover 12 is in place properly on probe head 13, probe 11 can be activated to enable its use for examination.

Sensor 16 provides data, such as an identification. The identification can include a lot number or serial number for cover 12. Alternatively, the identification can be a

different state of sensor 16, such as a different color if cover 12 had been previously used. Data from sensor 16 is forwarded to electronic unit 20 over link 19. Electronic unit 20 determines from the identification if cover 12 had been previously used. If it is determined cover 12 has not been previously used, electronic unit 20 can be adapted to activate probe 11 to enable its use for examination. If it is determined cover 12 has been previously used, electronic unit 20 can deactivate probe 11 to prevent its use for examination.

Sensor 16 can also provide an expiration date such as a manufacture date plus a shelf life over link 19. If it is determined cover 12 is expired, electronic unit 20 can deactivate probe 11 to prevent its use in examination. Sensor 16 can also provide calibration data to probe 11 for operation of probe head 13.

One or more sensors 17 receive information upon use of probe 11. Sensor 17 can be coupled to any position of cover 12. Alternatively, sensor 17 can be coupled to retaining means 15 or probe handle 14. Sensor 17 can link through probe handle 14 to electronic unit 20 over link 19. Data acquisition of probe 11 from sensor 17 can be forwarded over link 19 to electronic unit 20.

Sensor 16 can be an integrated circuit. Electronic unit 20 can include a processor, display device, storage unit and central unit. In one embodiment, electronic unit 20 can be a personal computer. Alternatively, electronic unit 20 can be housed in probe handle 14. In this embodiment, electronic unit 20 comprises a processor and storage unit. Data stored in electronic unit 20 of probe handle 14 can be later uploaded to a remote computing device, such as a personal computer.

Examples of sensor 17 include restive pad sensors such as manufactured by Tekscan or Vistamed, force sensitive register pads, such as manufactured by PPS, strain gages or MEMS pressure die. For example, link 19 can be a wireless link, optical link or direct electrical connection. Electronic coding of sensor 16 and sensor 17 can be performed by radio frequency (RFID) tag, RFID direct connect, EEPROM, electrical fuse, ink and barcode. For example, in the use of a RFID-tag or RFID direct connect a read/write integrated circuit is used in sensor 16 and/or sensor 17 in probe handle 14. In RFID-tag, sensor 16 or sensor 17 communicates over a wireless link to probe handle 14. In RFID-tag direct connect, sensor 16 or sensor 17 communicates over a direct link to

probe handle 14. In EEPROM, a plurality of electrical contacts are used to communicate between sensor 16 or sensor 17 to probe handle 14 to provide an erasable data, such as an identification number or serial number. Alternatively, for example, four electrical contacts can be used in EEPROM. In electrical fuse, electrical contacts are used to communicate between cover 12 and probe handle 14. For example, two electrical contacts can be used to form an electrical fuse. For example, in the use of ink, the ink can disappear from transparent to opaque upon exposure to heat, temperature or UV. An optical interrupter can be used to detect the change in the ink state. Accordingly, upon use of probe 11, probe handle 14 can transmit a wavelength of a predetermined intensity for changing the ink state of sensor 16 or sensor 17. In the case of a barcode, the barcode of sensor 16 or sensor 17 is written on cover 12 or on a label on cover 12. Electronic unit 20 can include a barcode reader for reading the barcode or the barcode reader can be located on probe 11.

Cover 12 can be formed to have a shape similar to the medical device to provide a barrier to protect the medical device. For example, as shown in Fig. 2A, cover 12 can have various cross sectional shapes along lines A-A of Fig. 2B, B-B of Fig. 2C and C-C of Fig. 2D which correspond to the shape of probe 11 and allow pivoting of probe head 13.

Coupling means 21 can be used to retain cover 12 on probe 11 in addition to retaining means 15. For example, coupling means 21 can be a hook.

In one embodiment, cover 12 can include pull-tab 22 which is pulled to remove cover 12 from probe 11. Pull-tab 22 is attached to reduced thickness portion 24 of cover 12. Reduced thickness portion 24 of cover 12 can tear when pull-tab 22 is pulled. Accordingly, after pull-tab 22 tears reduced thickness portion 24, probe 11 is unable to be re-used in a subsequent procedure and insures single use of cover 12.

Figs. 3A-3E illustrate an alternate embodiment of an intelligent medical barrier device 30 in accordance with the teachings of the present invention. Cover 29 is coupled to collar 30 at bonding portion 31 of cover 29, as shown in Fig. 3A.

Enable switch 32 is formed on portion 33 of probe handle 14, as shown in Fig. 3B and Fig. 3C. For example, portion 33 can have a circular or elliptical shape for receiving collar 30. Collar 30 can have a circular shape that can be transformed into an elliptical

shape upon receipt over an elliptical probe handle 14 or can have a circular shape to be received over a circular probe handle 14.

Enable switch 32 includes upper portion 34 and contact 35, as shown in Fig. 3D. Collar 30 includes protrusion 36 formed on inner surface 37 of end 38 of collar 30. Collar 30 has detail 40 formed on inner surface 37 of end 38 of collar 30. Probe handle 14 includes ledge 42 on portion 33 of probe handle 14. During operation, collar 30 slides over portion 33 of probe handle 14 until protrusion 36 contacts upper portion 34 of enable switch 32 and detail 40 fits into ledge 42 for snapping collar 30 in place on probe handle 14. Upon contact of protrusion 36 with upper portion 34 of enable switch 32, contact 35 is contacted to activate enable switch 32. Activation of enable switch 32 indicates cover 29 is in place properly on probe 11. Thereafter, contact with ledge 42 can release collar 30 for detaching cover 29 from probe handle 14, as shown in Fig. 3E.

Barcode label 44 can be attached to collar 30. Electronic unit 20 can include a barcode reader for reading the barcode 44 or the barcode reader can be located on probe 11. Alternatively, sensor 16 and/or sensor 17 can be attached to collar 30.

Cover 12 and cover 29 can be formed of a biocompatible barrier material. Suitable materials for cover 12 include polyurethane, terphalate polyethylene and silicone. Cover 12 and cover 29 can have a wall thickness in the range of about 0.0001 to about 0.015 inches. It is desirable that cover 12 is designed to prevent damage of sensor 16 or sensor 17. Cover 12 and cover 29 can be sterilized. Cover 12 and cover 29 can be packaged in a sealed sterilized pouch.

Collar 30 can be formed of a hard plastic material. Cover 12, cover 29 and collar 30 can be formed by dip molding, one or two shot injection molding, or liquid injection molding.

In alternate embodiments, cover 12 or cover 29 can have a shape to be compatible with any medical device, such as for example, a catheter, endoscope or ultrasound device. Sensor 16, sensor 17 or enable switch 32 can be designed to interact with the desired medical device.

In an alternate embodiment, data on the number of uses of different covers 12 or covers 29 with probe 11 is collected by electronic unit 20. Probe 11 is activated for a predetermined one or more number of times based on the collected data.

It is to be understood that the above-described embodiments are illustrative of only a few of the many possible specific embodiments which can represent applications of the principles of the invention. Numerous and varied other arrangements can be readily devised in accordance with these principles by those skilled in the art without departing from the spirit and scope of the invention.